K093002

OCT 2 8 2009

510(k) Summary

Trade Name:	Azur Peripheral HydroCoil Endovascular Embolization System – Detachable 35
Generic Name:	Vascular Embolization Coil
Classification:	Class II, 21 CFR 870.3300
Submitted By:	MicroVention, Inc 1311 Valencia Avenue Tustin, California U.S.A.
Contact:	Naomi Gong

Predicate Devices:

Number	Description	Clearance Date
K071939	Azur Peripheral HydroCoil Endovascular Embolization System-Pushable 35	January 11, 2008
K090168	Azur Peripheral Hydrocoil Endovascular Embolization System – Detachable 18	March 12, 2009

Device Description

The Azur Peripheral HydroCoil Endovascular Embolization System- Detachable 35 consists of an implantable coil attached to a delivery pusher. The coil system is delivered to the treatment site through the microcatheter. The proximal end of the delivery pusher is inserted to the detachment controller. The detachment controller is activated by the user and this detaches the coil. The Azur coils are designed for use with the Azur Detachment Controller, specifically designed for coil detachment.

Indication For Use

The intended use as stated in the product labeling is as follows:

The Azur Peripheral HydroCoil Endovascular Embolization Coil System is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

Verification and Test Summary Table

Bench Testing	Result
Visual inspection	Met established criteria
Dimensional inspection	Met established criteria
Simulated use testing	Met established criteria
Reposition time	Met established criteria
Detachment test	Met established criteria
Advancement/Retraction test	Met established criteria
Detachment element tensile test	Met established criteria
Coil initial tension test	Met established criteria
Coil tensile test	Met established criteria
Gel expansion	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Azur Peripheral HydroCoil Endovascular Embolization System – Detachable 35 coils when compared with the predicate devices, MicroVention Azur Pushable 35 [K071939] and Azur Detachable 18 [K090168].

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same material and processes.

In summary, the Azur Detachable 35 coils described in this submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MicroVention, Inc.
c/o Ms. Naomi Gong
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

OCT 2 8 2009

Re: K093002
Azur Peripheral HydroCoil Endovascular Embolization System-Detachable 35
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II (two)
Product Code: KRD
Dated: September 25, 2009
Received: September 28, 2009

Dear Ms. Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: Azur Peripheral HydroCoil Endovascular Embolization System – Detachable 35

Indications For Use:

The Azur Peripheral HydroCoil Endovascular Embolization Coil System is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K093602